

MONTGOMERY ANESTHESIA ASSOCIATES, P.C.

POST OFFICE BOX 235019
MONTGOMERY, AL 36123-5019
(334) 279-1450

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November 1, 2005

Division of Dockets Management (HFA -305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Number 2005P-0267

To Whom It May Concern:

Thank you for the opportunity to address you in regard to the above numbered docket. Because sedation with Propofol is a continuum, it is not always possible to predict how an individual patient will respond. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonist medications, agents such as propofol require special attention. Even if moderate sedation is intended, patients receiving propofol should receive care consistent with that required for **deep sedation and General Anesthesia**.

We believe that the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. The physician responsible for the use of Propofol sedation/anesthesia should have the education and training to manage the potential medical complications of sedation/anesthesia. The physician should be proficient in airway management, have advanced life support skills appropriate for the patient population, and understand the pharmacology of the drugs used.

The physician should be physically present throughout the sedation and remain immediately available until the patient is medically discharged from the post procedure recovery area.

The practitioner administering Propofol for sedation/anesthesia should, at a minimum, have the education and training to identify and manage the airway and cardiovascular changes which occur in a patient who enters a state of general anesthesia, as well as the ability to assist in the management of complications. If a practitioner is unable to manage these complications, patient deaths will be the unfortunate consequence.

The practitioner monitoring the patient should be present throughout the procedure and be completely dedicated to that task.

Therefore, we strongly feel that Propofol used for sedation or anesthesia "should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure." Appropriate monitoring and equipment must be available. If these conditions are not met, significant patient morbidity and mortality will result.

Sincerely,

A handwritten signature in cursive script, appearing to read "Rene A. Llera".

Rene A. Llera, M.D.
Jackson Hospital
Montgomery, Alabama

FB/blf